K032419

OCT 2 4 2003

# SECTION 3
# quantex D-DIMER - 510(k) Summary
# (Summary of Safety and Effectiveness)

**Submitted by:**

Instrumentation Laboratory Company
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**Contact Person:**

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

**Summary Prepared:**

August 4, 2003

**Name of the device:**

quantex D-DIMER

**Classification name(s):**

| | | |
|---|---|---|
| 864.7320 | Fibrinogen/fibrin degradation products assay | Class II |
| 81 DAP | Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control | |

**Identification of predicate device(s):**

K972696 IL Test D-Dimer

**Description of the device/intended use(s):**

Quantex D-DIMER is a latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on automated clinical chemistry analyzers.

The quantex D-DIMER Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer included in the quantex D-DIMER kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

**Statement of Technological Characteristics of the Device Compared to Predicate Device:**

Quantex D-DIMER is substantially equivalent to the commercially available predicate device IL Test D-Dimer in performance and intended use.

**Summary of Performance Data:**

In a method comparison study evaluating 137 citrated plasma samples, the correlation ($r$) of quantex D-Dimer on an ILab 600 compared to the predicate device on an ACL Futura was 0.987.

Within precision assessed over multiple runs using the quantex D-DIMER controls I/II on an ILab 600 gave a CV of 4.0% (at a mean of 302 ng/mL) and 2.2% (at a mean of 637 ng/mL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 24 2003

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: k032419
Trade/Device Name: quantex D-DIMER
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay
Regulatory Class: II
Product Code: DAP, GHH
Dated: September 16, 2003
Received: September 26, 2003

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** _____

**Device Name:** quantex D-DIMER

## Indications for Use:

Quantex D-DIMER is a latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on automated clinical chemistry analyzers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032419

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)